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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,723	08/10/2005	Nicolaas Duncas	2226-045890	1009
28289 7590 10/30/2008 THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219				
EXAMINER				
KEMMERER, ELIZABETH				
ART UNIT		PAPER NUMBER		
1646				
MAIL DATE		DELIVERY MODE		
10/30/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/518,723

**Applicant(s)**

DUNEAS, NICOLAAS

**Examiner**

Elizabeth C. Kemmerer, Ph.D.

**Art Unit**

1646

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 37-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application, Amendments, And/Or Claims***

The amendment received 28 August 2008 has been entered in full. Claims 1-35 are canceled. Claims 37-50 remain withdrawn from consideration. Claim 36 is under examination.

### ***Withdrawn Objections And/Or Rejections***

The objection to the specification for having an insufficiently descriptive title as set forth at p. 2 of the previous Office Action (mailed 28 April 2008) is *withdrawn* in view of the new title provided with the amendment received 28 August 2008.

### ***35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 36 remains rejected under 35 U.S.C. 103(a) as being unpatentable over either of Scott et al. or Yoshimura et al. in view of Kuberasampath et al., for the reasons set forth in the previous Office Action (mailed 28 April 2008).

Applicant's arguments (pp. 6-13, remarks received 28 August 2008) have been fully considered but are not found to be persuasive for the following reasons.

Applicant argues that none of the references teach using a 300 kDa membrane to produce a lower molecular weight fraction. Applicant further urges that using a 100 kDa membrane such as the prior art resulted in loss of bone morphogenic protein. This has been fully considered but is not found to be persuasive. The references clearly achieved isolation of bone morphogenic protein. The use of a 100 kDa membrane or a 300 kDa membrane would have been an obvious matter of choice, absent a showing of unexpected results. The prior art used a 100 kDa membrane and achieved isolation of bone morphogenic protein. The skilled artisan would have known that using a larger membrane, such as a 300 kDa membrane, would not have caused the loss of this protein, since it was in the smaller molecular weight fraction. Applicant's attention is respectfully directed to M.P.E.P. § 2144.05, section II, for a discussion of the obviousness of optimizing process parameters within the level of skill in the art, absent evidence of unexpected results.

Applicant presents new data in support of an assertion that the 300 kDa membrane yields unexpected results. This has not been considered. Applicant's attention is respectfully directed to 37 C.F.R. § 1.132, which states:

**When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section.**

The new evidence (data) in the remarks was not submitted by way of an oath or declaration, as required by 37 C.F.R. § 1.132. Therefore, it has not been considered.

**Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ECK/

27 October 2008

/Elizabeth C. Kemmerer/  
Primary Examiner, Art Unit 1646